Cigna Medical Coverage Policy

Subject **Percutaneous Vertebroplasty, Kyphoplasty, and Sacroplasty**

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Coverage Policy

Cigna covers percutaneous kyphoplasty as medically necessary when standard medical therapy has failed to alleviate symptoms and ANY of the following criteria is met:

- osteoporotic, osteolytic, osteonecrotic (i.e., Kummell disease), or steroid-induced vertebral compression fracture with persistent, debilitating pain unresponsive to at least six weeks of conservative medical management
- severe back pain secondary to destruction of vertebral body due to osteolytic vertebral metastasis or multiple myeloma
- painful and/or aggressive hemangioma or eosinophlic granuloma of the spine

Cigna covers percutaneous vertebroplasty as medically necessary when standard medical therapy has failed to alleviate symptoms and EITHER of the following criteria is met:

- severe back pain secondary to destruction of vertebral body due to osteolytic vertebral metastasis or multiple myeloma
- painful and/or aggressive hemangioma or eosinophilic granuloma of the spine

Cigna does not cover percutaneous vertebroplasty or kyphoplasty for any other indication because each is considered experimental, investigational, or unproven.

Cigna does not cover percutaneous sacroplasty for any indication because it is considered experimental, investigational, or unproven.

General Background

Percutaneous vertebroplasty is a minimally invasive procedure in which bone cement (e.g., polymethylmethacrylate [PMMA]) is injected into a diseased vertebral body under fluoroscopic and/or computed tomography (CT) guidance. Percutaneous kyphoplasty, also referred to as balloon-assisted vertebroplasty, balloon kyphoplasty, or percutaneous vertebral augmentation, was developed as a modification of vertebroplasty. It includes expansion of the vertebra with an inflatable balloon tamp prior to the injection of bone cement. Both procedures have been used to treat osteoporotic vertebral compression fractures and vertebral fractures resulting from osteolytic destruction secondary to malignancy. Sacroplasty, a more recent variation of vertebroplasty, involves injection of PMMA into the sacrum for the treatment of sacral insufficiency fractures. These procedures have been proposed as alternatives to medical management to alleviate pain, provide spine stability and prevent further vertebral collapse in patients with vertebral compression fractures. Conservative medical management of osteoporotic vertebral fractures may include analgesics, activity modification, bracing, physical therapy, and medications including calcitonin, strontium ranelate, or ibadronate may be provided in an attempt to prevent future fractures. For patients with osteolytic destruction secondary to malignancy, these procedures have been proposed as alternatives to medical management, localized radiation therapy, and traditional surgical stabilization.

Vertebroplasty and kyphoplasty are contraindicated in burst fractures, which result from extreme force applied straight down on the vertebrae, and involve compression of both the anterior and middle columns. Burst fractures can be unstable if the posterior column has sustained injury, and may result in spinal cord injury. Additional contraindications include pedicle fractures, spinal canal or neural foramen compromise, cortical disruption, infection, myelopathy, coagulopathy, allergy to device or material, radiculopathy symptoms, pregnancy, high energy trauma, severe cardiopulmonary deficiencies, active osteomyelitis of the target vertebra, asymptomatic vertebral body compression fracture of patient improving with medical therapy, and use as prophylaxis in osteoporotic patients.

U.S. Food and Drug Administration (FDA)
Several bone cements received 510(k) approval in 2004–2005 for use in vertebroplasty and/or kyphoplasty, including KyphX® HV-R™ Bone Cement (Kyphon Inc., Sunnyvale, CA); Symphony™ VR Radiopaque Bone Cement (Advanced Biomaterial Systems, Inc. Chatham, NJ; and Parrallax® Acrylic Resin with TRACERS® (ArthroCare Corp., Sunnyvale, CA. Numerous additional manufacturers subsequently received 510(k) FDA approval for bone cement for use in vertebroplasty and kyphoplasty.

Percutaneous Vertebroplasty
Percutaneous vertebroplasty was first reported in France in 1987 as a treatment for complicated vertebral body hemangioma. The procedure has since been investigated as a treatment to provide mechanical support and pain relief for other conditions associated with osteolytic destruction of the spine. Reported uses of percutaneous vertebroplasty include treatment of osteoporotic fractures, vertebral metastasis, vertebral involvement of multiple myeloma, and, less frequently, aggressive vertebral hemangiomas, Langerhans cell histocytosis, (i.e., eosinophilic granuloma), and vertebral lymphoma. The mechanism of pain relief attributed to vertebroplasty is not well understood. It has been proposed that pain relief is achieved through stabilization of a weakened vertebral body or by thermal damage to intraosseous nerve fibers.

Percutaneous vertebroplasty gained acceptance by some practitioners as a safe and effective method to provide pain relief, increased mobility and improved quality of life for patients with painful osteolytic lesions and osteoporotic compression fractures. This acceptance and subsequent expanded use of the procedure was primarily based on evidence from uncontrolled studies, however. Until recently, the available literature indicated that these procedures could provide effective treatment with few complications in selected patients. It is likely that the placebo effect as well as the natural history of vertebral fractures contributed in some cases to reported improvements, however, and the safety and efficacy of vertebroplasty had not been evaluated in randomized controlled trials. Two randomized sham-controlled trials published in 2009 demonstrated a lack of improved outcomes with vertebroplasty compared to a sham procedure in the treatment of osteoporotic vertebral compression fractures. These studies constitute the highest quality evidence published to date. In addition, the use of vertebroplasty has been questioned by recently published technology assessments and specialty society guidelines, detailed below. Guidelines from the American Academy of Orthopaedic Surgeons published in 2010, based on a systematic review of studies published in peer reviewed journals, strongly recommend against vertebroplasty for the treatment of osteoporotic spinal compression fractures. Although vertebroplasty is a

minimally invasive procedure, it is not without risk of complications. Complications may include localized bleeding, infection, and pain or neurological symptoms following leakage of injected materials. Although rare, injected material may leak into the venous circulation, potentially resulting in pulmonary embolism.

Literature Review: A single-center randomized controlled trial conducted by Farrokhi et al. (2011) was conducted to evaluate percutaneous vertebroplasty (n=40) vs. optimal medical care (n=42) in controlling pain and improving quality of life in patients with vertebral compression fractures. Greater improvement was seen in the mean visual analog score (VAS) in the vertebroplasty group than in the optimal medical treatment group at one week (3.3 ± 1.5 vs. 6.4 ± 2.1, p<0.001); six months (2.2 ± 2.1 vs. 4.1 ± 1.5, n<0.021); and 12 months (2.2 ± 2.1 vs. 4.1 ± 1.8, n<0.11). Improvement in Oswestry disability scores for up to 24 months was also greater in the vertebroplasty group compared to the optimal medical therapy group. It is unclear whether evaluators were blinded regarding treatment assignment. Two and three years after treatment, differences in pain and disability were not significant. Patients in the optimal medical therapy group were allowed to undergo vertebroplasty after one month (crossover); within 24 months, 10 of 42 patients in the medical therapy group underwent vertebroplasty.

Klazen et al. conducted an open-label randomized trial to determine whether vertebroplasty has additional value compared with optimum pain treatment in patients with acute vertebral fractures. The study used the following inclusion criteria: vertebral compression fractures on spine radiograph, minimum 15% height loss, fracture at T5 or lower, bone edema on magnetic resonance imaging (MRI), back pain for six weeks or less, and a visual analog score (VAS) of five or more. Of 431 patients eligible for randomization, 229 (53%) had spontaneous pain relief during assessment and did not participate. Of the remaining 202 patients with persistent pain, 101 were randomized to vertebroplasty and 101 to conservative treatment. Vertebroplasty resulted in greater pain relief than conservative treatment; the difference in mean VAS score between baseline and one month was -5.2 after vertebroplasty and -2.7 after conservative treatment, and between baseline and one year was -5.7 after vertebroplasty and -3.7 for conservative treatment. Interpretation of the results of this study is difficult; the analysis included a responder analysis as a primary outcome; a clinically significant change in pain was defined a priori as a three point difference on the VAS scale, and although patients couldn't be blinded to group assignments, no attempt was made to blind treatment assignment for those assessing outcome. In addition, 10% of the patients in the conservative treatment crossed over to the vertebroplasty arm, but details regarding how and when these crossovers occurred is not provided (WA Health Technology Assessment, 1010; Blue Cross Blue Shield Technology Evaluation Center [TEC], 2011).

Buchbinder et al. (2009) conducted a multicenter, randomized double-blind controlled trial to determine the short-term efficacy and safety of vertebroplasty for alleviating pain and improving physical functioning in patients with osteoporotic vertebral fractures (n=78). Patients with one or two painful osteoporotic vertebral fractures of less than 12 months duration, confirmed as unhealed by magnetic resonance imaging (MRI), were randomly assigned to vertebroplasty (n=38) or a sham procedure (n=40). Outcomes were evaluated at one week and at one, three, and six months. The primary outcome was overall pain at three months. In the vertebroplasty group, the left pedicle of the fracture site was identified, the skin overlying the pedicle was infiltrated with a 25-gauge needle, and the periosteum of the posterior lamina was infiltrated with a 23-gauge needle. An incision was made in the skin, and a 13-gauge needle was placed posterolaterally relative to the eye of the pedicle. Gentle tapping guided the needle through the pedicle into the anterior two thirds of the fractured vertebral body. PMMA was then injected into the vertebral body. Patients in the sham intervention group underwent the same procedure up until the insertion of the 13-gauge needle. To simulate vertebroplasty, the vertebral body was gently tapped, and PMMA was prepared so that he smell permeated the room. Of the 78 enrolled patients, 35 of 38 in the vertebroplasty group and 36 of 40 in the placebo group completed the six month follow-up. Vertebroplasty did not result in a significant advantage in any measured outcome at any time point. There was a significant reduction in overall pain in both groups at each assessment. Similar improvements were seen in both groups for pain at night and at rest, physical functioning, quality of life, and perceived improvement. The authors concluded that no significant benefit of vertebroplasty over a sham procedure was demonstrated after six months of follow-up, and that these findings call into question the use of vertebroplasty in such patients.

Kallmes et al. (2009) conducted a multicenter randomized, double-blind controlled trial to evaluate the efficacy of vertebroplasty in the treatment of painful osteoporotic compression fractures (n=131). Patients were randomized to receive vertebroplasty with PMMA (n=68) or a simulated procedure without PMMA (n=63). For all patients, the skin and subcutaneous tissues overlying the pedicle of the target vertebra or vertebrae were infiltrated with lidocaine, and the periosteum of the pedicle was infiltrated with bupivacaine. Patients were then

randomly assigned to receive vertebroplasty or the control intervention. In the vertebroplasty group, needles were passed into the central aspect of the target vertebra or vertebrae, and PMMA was infused. During the control intervention, verbal and physical cues (e.g., pressure on the patient's back) were given, and the methacrylate monomer was opened to simulate the odor of PMMA, but the needle was not placed and PMMA was not infused. The primary outcomes were scores on the modified Rolan-Morris Disability Questionnaire (RDQ) (on a scale of 0–23, with higher scores indicating greater disability), and patients' rating of average pain intensity during the preceding 24 hours at one month (on a scale of 0–10, with higher scores indicating more severe pain). At one month, there was no significant difference between the two groups in the RDQ score (p=0.49) or the pain rating (0=0.19). Both groups had immediate improvement in disability and pain scores after the intervention. Although the groups did not differ significantly on any secondary outcome measure at one month, there was a trend toward a higher rate of clinically meaningful improvement in pain in the vertebroplasty group (p=0.06).

Staples et al. (2011) conducted a meta-analysis of combined individual patient level data from the two multicenter randomized controlled blinded trials of vertebroplasty (Buchbinder et al., 2009; Kallmes et al., 2009), discussed above, to determine whether vertebroplasty is more effective than placebo for patients with pain of recent onset (≤ six weeks) or severe pain (score ≥ 8 on a 0–10 numerical rating scale. The authors stated that, despite the negative findings of these two trials, it has been suggested that there may be subgroups of patients who would benefit from vertebroplasty. The suitability of vertebroplasty for some of the trial participants has also been questioned. Some have maintained that vertebroplasty should only be offered to patients with recent acute vertebral fractures (< six weeks), while others claim it is more effective for those with severe pain. Although neither trial found evidence that symptom duration was a treatment effect modifier, individually the trials lacked sufficient power to draw definitive conclusions from subgroup analysis. The authors therefore combined individual patient level data from both trials to evaluate symptom duration and to investigate smaller benefits in pain or function. For patients with pain of recent origin, between-group differences in mean change scores at one month for pain and disability were 0.1 and 0.2, respectively. For those with severe pain at baseline, between-group differences for pain and disability scores at one month were 0.3 and 1.4, respectively. At one month those in the vertebroplasty group were more likely to be using opioids. Individual patient data meta-analysis, powered for subgroup analysis, failed to show an advantage of vertebroplasty over placebo for patients with recent onset fracture or severe pain.

Diamond et al. (2003) conducted a prospective case-control study in which 79 consecutive osteoporotic patients with acute vertebral fractures were treated with percutaneous vertebroplasty (n=55) or conservative therapy alone (n=24). All patients presented to the emergency department or were inpatients at a hospital in Australia. Patients who met the inclusion criteria were offered vertebroplasty. Patients who declined the procedure and agreed to longitudinal evaluation comprised the control group. The mean follow-up period was 215 days (range 57–399). Twenty-four hours after vertebroplasty there was a 53% reduction in pain scores from 19 to nine, as measured by the VAS, and a 29% improvement in physical functioning from 14 to 18, as measured by Barthel Index. There was no change in VAS and Barthel Index scores for patients in the conservatively treated group at 24 hours. Clinical outcomes at six weeks and 6–12 months were similar in both groups, however. The authors concluded that when compared to conservative therapy, percutaneous vertebroplasty results in prompt pain relief and rapid rehabilitation. The authors also stated that carefully designed and well-executed long-term clinical trials are needed to verify that this procedure is effective and superior to conservative therapy for managing acute osteoporotic vertebral fractures.

Vertebroplasty has been evaluated in several prospective case series for treatment of osteoporotic vertebral fractures McGraw et al. (2002) reported that 93% of patients achieved significant improvement in back pain as well as improved ambulatory ability at a mean follow-up of 21.5 months. The preoperative mean VAS score was 8.9 ± 1.12 compared to a score of 2.02 ± 1.95 at follow-up. Winking et al. (2004) evaluated treatment-related disability and quality of life using the Oswestry Low Back Pain Disability (OLBPD) Questionnaire. Preoperative OLBPD scores were 3.7 ± 0.2 preoperatively, compared to scores of 1.6 ± 0.1 at six weeks. The median preoperative VAS pain score was seven, compared to median postoperative scores of 1.8 at two days, 2.6 at six weeks, and 2.7 at six months and one year.

The studies described above evaluate vertebroplasty for osteoporotic fractures. Published studies evaluating vertebroplasty for treatment of osteolytic destruction (e.g., metastasis) consist primarily of retrospective case series. Deramond et al. (1998) conducted an early case series evaluating vertebroplasty in 234 patients with pain caused by vertebral hemangioma, osteoporotic collapse or metastasis, or myeloma. The authors reported

that percutaneous vertebroplasty was effective in relieving pain and restoring mobility in 92% of patients. These benefits were maintained for patients with nonprogressive conditions, although the period of follow-up was variable, and the details of outcome measures were not reported.

Several additional retrospective case series have evaluated percutaneous vertebroplasty in the treatment of fractures due to malignancy. Alvarez et al. (n=21, 2003) reported improvement in VAS score from 9.2 preoperatively to 3.0 at three months, with no major complications. Fourney et al. (n=34, 2003) reported improvement in VAS score from eight preoperatively to two at one month. In the study by Chow et al. (n=15, 2004) the VAS score improved from 10 with movement and seven at rest to one with movement and zero at rest at 2–12 weeks follow-up. Cement leakage was reported in each of these studies, although most patients had no associated symptoms. These studies demonstrate significant short-term pain relief as measured by VAS. It is difficult to draw conclusions from these studies, however, because of the study design and small number of included patients.

Percutaneous Kyphoplasty
Kyphoplasty, also referred to as balloon-assisted vertebroplasty, balloon kyphoplasty, or percutaneous vertebral augmentation, was introduced in 2001 as a variation of percutaneous vertebroplasty. A specialized bone tamp with an inflatable balloon is used to expand a collapsed vertebral body to approximate its natural height. Mechanical fixation of the vertebral body is performed by injecting PMMA into the expanded cavity using lower pressure, although PMMA leakage outside the vertebral cavity can still occur. Complications of percutaneous kyphoplasty are similar to those seen with vertebroplasty and are relatively rare. Complication rates are highest in patients with malignancy, due to cement leakage from lytic regions in the vertebral bodies. Reported complications are also higher in this population due to poor overall health.

Literature Review: A randomized unblinded controlled trial was conducted by Berenson et al. (2011) to assess the efficacy and safety of kyphoplasty in patients with cancer and vertebral compression fractures (n=134). Patients with cancer and one to three painful VCFs were randomized to kyphoplasty (n=70) or non-surgical management (n=64).Non-surgical treatment was not standardized; each study center was asked to provide care consistent with local practice. The primary endpoint was back-specific functional status as measured by the Roland-Morris disability questionnaire (RDQ) score at one month. At one month, 65 patients in the kyphoplasty group and 52 in the control group had data available The mean RDQ score in the kyphoplasty group changed from 17.6 at baseline to 9.1 at one month ($p<0.0001$). The mean control group score changed from 18.2 to 18.0 ($p=0.83$). The kyphoplasty treatment effect for RDQ was -8.4 points at one month ($p<0.0001$). At one month, patients were able to cross over to the kyphoplasty group from the control group, preventing long-term analysis of the randomized population.

Wardlaw et al. (2009) conducted a multisite randomized controlled trial to assess the efficacy and safety of balloon kyphoplasty in the treatment of painful vertebral fractures (n=300). Fractures were a mean of 5.6 weeks old at randomization in the kyphoplasty group and 6.4 weeks old in the control group. Inclusion criteria consisted of one to three vertebral fractures. At least one fracture was required to have edema assessed by MRI and at least one fracture had to show at least 15% loss of height. Patients were randomized to kyphoplasty treatment (n=149) or to non-surgical care (n=151). The primary outcome was the difference in change from baseline to one month in the short-form (SF)-36 physical component summary score (scale 1–100). One month follow-up was completed by 138 of 149 kyphoplasty patients and 128 of 151 control patients. Mean SF-36 scores improved by 7.2 points at one month in the kyphoplasty group, and by 2.0 points in the non-surgical group ($p<0.0001$). At 12 months, the difference between kyphoplasty and control had diminished. The authors suggested that improvement in the non-surgical group during the 12 month follow-up was likely due to fracture healing.

Boonen et al. (2011) published two-year results of the Wardlaw study (above). Quality of life, function, disability, and pain were assessed over 24 months. Most outcome measures for kyphoplasty compared to medical treatment were improved when averaged over the 24 month period, but were not significantly different at 24 months. There was no significant difference in physical symptoms between groups, as assessed by the 100-point PCS component of the SF-36 at 24 months ($p=.15$). The kyphoplasty group had a greater improvement in the 10-point back pain score that was maintained at 24 months (-80 points, $p=.009$). There was no significant difference between groups in the number of subsequent adjacent fractures; approximately 50% of patients in the study had subsequent vertebral fractures that were brought to clinical attention because of renewed pain. Two

serious adverse events occurred more than a year following kyphoplasty; a recollapse of a treated vertebra with anterior migration of the cement, and a case of spondylitis.

Garfin et al. (2006) conducted a prospective multicenter case series to evaluate the safety and effectiveness of kyphoplasty in the treatment of symptomatic vertebral compression fractures. Quality of life was measured using the Standard Form (SF) 36. Mean preoperative scores on five of the eight subscales were significantly diminished, at ≤ 60% of the age and sex-matched normal values. The mean preoperative scores were 6.3 for role physical, 19.0 for bodily pain, 29.9 for physical function and 37.8 for social function. At 24 months follow-up, mean scores improved to 49.7 for role physical, 52.1 for bodily pain, 46.1 for physical function, and 73.5 for social function. The mean index of back function total back disability score improved from 1.4 at baseline to 0.6 at one month, 0.5 at three and twelve months, and.0.4 at 24 months. As judged by the treating physician, extravasation of PMMA outside the vertebral body occurred in 21 of 214 (10%) treated levels. Review of 165 cases by an independent radiologist showed similar findings, with a PMMA extravasation rate of 11%. During the follow-up period, 23 (23%) patients had at least one subsequent painful vertebral compression fracture. Fourteen of these 23 fractures occurred adjacent to a kyphoplasty-treated vertebral body. Of 155 patients enrolled, 55 did not complete the 24 months of follow-up.

Kasperk et al. (2005) conducted a prospective nonrandomized cohort study to evaluate kyphoplasty in the treatment of patients with vertebral fractures and chronic pain of more than 12 months' duration. Patients self-selected to kyphoplasty or standard medical treatment (n=40) or standard medical treatment alone (n=20). All patients were offered kyphoplasty, and those who refused formed the control group. Outcomes were assessed at three and six months. Pain was evaluated using a modified VAS scoring system, and the European Vertebral Osteoporosis Study (EVOS) score was used to evaluate daily activities. Greater improvement in VAS and EVOS scores and fewer pain-related physician visits were reported in the kyphoplasty group than in the control group. The authors concluded that kyphoplasty is a promising addition to current medical treatment in appropriately selected patients but acknowledged that these findings require confirmation by randomized controlled trials. **3**

A prospective nonrandomized comparative study (Grohs, et al., 2005) evaluated the mechanical effects and impact on quality of life over a two year period in patients with vertebral compression fractures treated with kyphoplasty (28 patients/35 kyphoplasties) or vertebroplasty (23 patients/29 vertebroplasties). There were no significant differences between the groups in terms of patient age and age of fractures. In the kyphoplasty group the VAS score was 7.4 before surgery, 3.5 one day after surgery, 3.2 at four months and 2.0 at two years. The OLBD score for the kyphoplasty group was 61% before surgery, decreased to 42% at one year, but increased to 56% at two years. In the vertebroplasty group the VAS score was 7.8 prior to surgery, 3.0 one day after surgery, 5.7 at four months and 5.6 at two years. The OLBD score was 49% before surgery, decreased slightly to 46% at one year, and increased to 52% at two years. The authors concluded that patients with non-recent fractures seem to experience a longer-lasting effect on pain after balloon kyphoplasty, although they experienced a higher rate of subsequent compression fractures in adjacent levels. Although the decrease in pain persisted at two years, improvement in disability was limited to one year.

Lane et al. (2004) conducted a prospective case series to evaluate kyphoplasty in the treatment of vertebral fractures due to multiple myeloma (n=19). The authors reported meaningful improvement in 16 of 19 patients at three months. OLBD scores improved from 49 ± 16.6 to 32.6 ± 13.6. Improvement in vertebral body height was also reported. The results were compared with those of a cohort of 26 patients treated for osteoporotic compression fractures. There was no difference in OLBD improvement between the two groups, but greater anterior vertebral height restoration was seen in the osteoporotic group. The authors concluded that kyphoplasty is a safe treatment for myeloma-related vertebral compression fractures with efficacy in terms of pain relief and functional outcomes that are comparable to results of patients with osteoporosis. The authors also stated that it is unclear how many levels with fractures related to multiple myeloma should have kyphoplasty, or whether vertebral bodies that show ongoing deformity but are painless are candidates for kyphoplasty, and that well-controlled prospective studies are needed to answer these questions.

Several small case series focused on kyphoplasty to treat vertebral fractures due to malignancy. Dudeney et al. (2002) conducted a prospective case series evaluating kyphoplasty in 18 patients (55 vertebral bodies) with vertebral compression fractures resulting from multiple myeloma. At a mean follow-up of 7.4 months, improvements from baseline in SF 36 scores for pain (from 33.2 to 55.4), physical function (from 21.3 to 50.6), and social functioning (from 31.3 to 47.5) were reported. The authors also reported that on average, 34% of height lost at the time of fracture was restored.

Several additional case series evaluated kyphoplasty in the treatment of vertebral fractures reported improvement in pain and functional scores at short-term follow-up ranging from one week to 18 months (Rhyne at al., 2004; Lieberman et al., 2001 Ledlie and Renfro, 2003; Phillips et al., 2003; Gaitanis, et al., 2005; Ledlie and Renfro, 2006).

Percutaneous Sacroplasty
Percutaneous sacroplasty, a variation of vertebroplasty, is an evolving technique that has been proposed for the treatment of sacral insufficiency fractures. Under fluoroscopic guidance, PMMA is injected through a needle inserted into the sacrum at the fracture site.

Literature Review:
Bayley et al. (2009) performed a review of the literature to identify the various techniques used for surgical treatment of sacral insufficiency fractures and to evaluate their outcomes. The techniques described included sacroplasty with or without augmented iliosacral screws. No level I, II, or III evidence was available, and only five articles provided follow-up of one year or more. At total of 108 patients were included in the analysis. The authors concluded that results of cement augmentation techniques such as sacroplasty are promising, with immediate pain relief and maintenance of benefit in the medium-to long-term, but questions remain. The optimal technique and long term outcomes of this procedure need further analysis. The authors stated that future prospective clinical studies with an independent observer to analyze he long-term success rate and complications of this procedure are warranted.

Frey et al. published two case series to assess sacroplasty for the treatment of sacral insufficiency fractures. A study published in 2008 evaluated outcomes and complication rates in 52 patients with incapacitating lumbar and/or gluteal pain, with failure of or intolerance to conservative measures. The mean VAS was 8.1 at baseline, 3.6 thirty minutes following the procedure, 2.5 at two weeks, 2.1 at four weeks, 1.7 at 12 weeks, 1.4 at 24 weeks, and 0.8 at 52 weeks. Improvement was statistically significant. The case series published in 2007 evaluated the safety and efficacy of sacroplasty in 37 patients with sacral insufficiency fractures. VAS scores were monitored periodically for one year, and analgesic usage and patient satisfaction were assessed at the final follow-up. The mean VAS score was 7.7 at baseline, 3.2 within 30 minutes, 2.1 at two weeks, 1.7 at four weeks, 1.3 at 12 weeks, 1.0 at 24 weeks, and 0.7 at 52 weeks post-procedure. At baseline, 20 patients were using narcotic analgesics compared to 12 patients at last follow-up. The procedure was terminated in one patient who developed radicular pain prior to the injection of PMMA that persisted following the procedure. The authors noted in both studies that the natural history of osteoporotic sacral insufficiency fractures is gradual improvement starting within one to two weeks of treatment initiation, but considered it unlikely that regression toward the mean accounted for the rapid pain reduction seen in this study. The authors also acknowledged in both studies that, because of the lack of a control group, a placebo effect could not be excluded.

Systematic Reviews
Eck et al. (2008) conducted a meta-analysis of the literature to evaluate pain relief and risk of complications associated with vertebroplasty vs. kyphoplasty. Studies included prospective randomized and non-randomized trials, retrospective reviews, and case reports. Studies that provided specific VAS scores were included, and studies and case reports that provided information on complications were also included. A total of 168 studies met the inclusion criteria. Mean pre-and postoperative VAS scores for vertebroplasty were 8.36 and 2.68, respectively, with a mean change of 5.68 ($p<.001$). Mean pre-and postoperative VAS scores for kyphoplasty were 8.06 and 3.46, respectively, with a mean change of 4.60 ($p<.001$). Greater improvement was seen with vertebroplasty vs. kyphoplasty ($p<.001$). The risk of new fractures was 17.9% with vertebroplasty compared to 14.1% with kyphoplasty ($p<.01$). The risk of cement leak was lower with kyphoplasty than vertebroplasty, at 7.0% vs. 19.7%, respectively ($p<.001$). The majority of cement leaks were asymptomatic, incidental findings.

Gill et al. (2007) conducted a systematic review and meta-analysis comparing pain reduction following vertebroplasty and kyphoplasty performed for osteoporotic vertebral compression fractures. Fourteen vertebroplasty and seven kyphoplasty prospective and retrospective trials qualified for inclusion, representing 1046 vertebroplasty patients and 263 kyphoplasty patients. Both procedures resulted in a reduction of greater than five points in the VAS in the immediate postoperative period ($p<0.00001$). The difference in pain relief was not significant between the two procedures. At final follow-up, the VAS for both vertebroplasty and kyphoplasty was improved, but this improvement was not considered significant when compared to the preoperative VAS

(p=0.25, p=0.38, respectively). The authors stated that randomized controlled trials are needed to determine which procedure is most effective for vertebral compression fractures.

Bouza et al. (2006) conducted a systematic review of the literature and meta-analysis of clinical studies evaluating the efficacy and safety of balloon kyphoplasty in the treatment of vertebral compression fractures. A total of 26 studies met the inclusion criteria. The results of the clinical series indicate significant improvements in pain intensity, vertebral height, sagittal alignment, functional impairment and quality of life, although studies displayed considerable methodological limitations. The authors also reported that, compared with vertebroplasty, kyphoplasty reduced the loss of height and kyphotic deformity with a lower leakage rate. Leakage affected 7% of patients; complications were seen in 2% of patients; and new vertebral fractures were seen in 16% of patients. The authors of this systematic review concluded that available evidence suggests that kyphoplasty can be effective and safe for the treatment of vertebral compression fractures, but existing studies demonstrate substantial methodological limitations and relatively short follow-up periods. The authors stated, "Better clinical research is required to determine the capacity of balloon kyphoplasty to avoid the functional and physiological sequelae of vertebral compression fractures and to define the true role of the technique among the existing therapeutic options."

Hulme at al. (2006) conducted a systematic review of 69 clinical studies to evaluate the safety and efficacy of vertebroplasty and kyphoplasty. The authors reported that some pain relief was obtained in 87% of vertebroplasty patients and 92% of kyphoplasty patients. Vertebral height restoration was possible using kyphoplasty (average 6.6 degrees) and a subset of vertebroplasty patients (average 6.6 degrees). Cement leakage was the most common complication, and was reported in 41% of vertebroplasty procedures and 9% of kyphoplasty procedures. The authors stated that, although considerable cement leakage has been reported, the actual rate of leakage may have been underreported because of reporting bias or the detection method used. Cement leakage was asymptomatic in 96% of vertebroplasty patients and 89% of kyphoplasty patients. The authors stated that, until asymptomatic cement leakage can be disregarded as irrelevant, CT is the best method to monitor leakage. New fractures of adjacent vertebrae occurred following both procedures. The authors stated that it has not been determined whether this is caused by altered loading, increased patient activity or the natural progression of osteoporosis. The authors concluded that it cannot be definitively stated that vertebroplasty and kyphoplasty are safe and effective procedures because of a lack of comparative, blinded, randomized clinical trials. The authors further stated that the adoption of standardized reporting and methodology and an increase in methodological quality would enhance comparability, validity and applicability of the studies.

Taylor et al. (2006) conducted a comparative systematic review of the efficacy and safety of balloon kyphoplasty (four nonrandomized comparative studies and 13 case series) and vertebroplasty (two nonrandomized comparative studies and 57 case series) for vertebral compression fractures, and updated the review in 2007 to include four additional comparative studies and 21 case series. Five studies compared kyphoplasty to vertebroplasty and three to conventional medical care for 481 fractures in 313 patients. The case series included 2047 patients treated with kyphoplasty on 3301 vertebral levels. The median duration of follow-up ranged from hours up to 37 months post-procedure. The limited level of reporting of methods hindered evaluation of methodological quality. The studies that directly compared kyphoplasty to medical care demonstrated significant pain reduction with kyphoplasty, as measured by VAS at 3, 6, 12 and 36 months, and this reduction in pain was greater with kyphoplasty than with medical care alone. Five studies compared kyphoplasty to vertebroplasty. Both procedures reduced VAS pain and improved Oswestry disability index scores for up to 24 months post-procedure, with no significant difference between procedures. All case series in the systematic review reported reduction in pain after kyphoplasty. Studies that evaluated vertebral height and kyphotic angle correction reported improvements in favor of kyphoplasty, with an average improvement in vertebral height of 21% and reduction of 6.3 degrees in kyphotic angle. Safety outcomes of kyphoplasty were combined for comparative studies and case series. A total of 28 studies included details of cement leakages, and eight of these reported whether the leaks were symptomatic or not. A total of 189 (9%) cement leakages were reported in 2239 vertebrae. One leak was reported to be symptomatic, resulting in radiculopathy. A total of 171 new or incident fractures were reported in 1151 patients/16 studies, with 64% of these occurring in adjacent vertebrae. Two of the studies reported fewer subsequent fractures in patients treated with kyphoplasty, however, compared to those who received conventional medical care. The authors concluded that kyphoplasty is more effective than medical management of osteoporotic vertebral compression fractures and is at least as effective as vertebroplasty.

Technology Assessments

Blue Cross Blue Shield Association Technology Evaluation Center (TEC): A BCBS TEC Assessment (in press, Feb, 2011) evaluated the available evidence to determine whether either percutaneous vertebroplasty or kyphoplasty improved the net health outcome for individuals with painful vertebral fractures caused by osteoporosis. The assessment updated the 2010 assessment, incorporating additional studies, including the double-blind, randomized sham control trials by Kallmes (2010) and Buchbinder (2010), and the open label randomized trial by Klazen (2010), all described above. The assessment concluded that the two randomized double-blind controlled trials provide evidence that vertebroplasty may not improve health outcomes when compared to a sham procedure. Because both trials were underpowered, these results should be interpreted as uncertainty rather than a lack of effect. The trial by Klazen investigated vertebroplasty in patients with acute fracture, unlike the participants enrolled in the placebo-controlled trials, and due to methodological issues, interpretation of these data is unclear. The assessment also concluded that the evidence is insufficient to determine if vertebroplasty improves the net health outcome or is as beneficial as any established alternatives. For these reasons, vertebroplasty for vertebral fractures from osteoporosis does not meet the TEC criteria.

The TEC assessment conclusions regarding kyphoplasty remain unchanged from the previous assessment. It is not possible to quantify the benefit of the procedure, or to determine if kyphoplasty improves the net health outcome or is as beneficial as any established alternative. Percutaneous kyphoplasty for vertebral fractures from osteoporosis does not meet the TEC criteria.

Washington State Health Care Authority Health Technology Assessment: A Washington State Health Technology Assessment, Vertebroplasty, Kyphoplasty and Sacroplasty, was published in November, 2010, based on a structured, systematic search of the peer reviewed literature. In summarizing the purpose of the review, the authors noted that these procedures are less invasive than other spinal surgical procedures, but more invasive than conservative medical therapy, and although non-randomized studies have reported improvements in pain and functioning, significant questions remain about the safety, efficacy, effectiveness, and cost-effectiveness of these procedures.

The assessment provided the following conclusions:

Efficacy

- Vertebroplasty
  - Pain relief: Uncertain whether vertebroplasty is effective for pain relief.
  - Function and quality of life: Uncertain whether vertebroplasty improves patient functioning and quality of life

- Kyphoplasty
  - Pain relief: Uncertain whether kyphoplasty is effective for pain relief.
  - Function and quality of life: Uncertain whether kyphoplasty improves patient functioning and quality of life

- Vertebroplasty compared with kyphoplasty
  - Pain relief: A single poor-quality RCT found equal improvement in back pain scores over six months. The strength of evidence was noted to be very low.

  - Function and quality of life: No evidence of efficacy for these outcomes.
- Sacroplasty: No evidence of efficacy since the only available evidence consists of case series.

Effectiveness

- Vertebroplasty
  - Pain relief: Uncertain whether vertebroplasty is more effective than conservative medical treatment in reducing pain. Four nonrandomized studies with follow-up of up to a year found that vertebroplasty was more effective than conservative medical treatment up to approximately six months. Pain levels were comparable at one year in both groups. The strength of evidence was noted to be very low.

    - Function and quality of life: A similar pattern was seen in improvements in these four studies in functioning and quality of life, with superior effectiveness in the first 3-6 months followed by equivalent levels of functioning at one year. The strength of evidence was noted to be very low.

- Kyphoplasty:
    - Pain relief: In two non-randomized studies, kyphoplasty reduced pain more than conservative medical treatment for periods up to three years.
    - Function and quality of life: In these two studies, kyphoplasty improved a limited set of functional outcomes more than conservative medical treatment.

- Vertebroplasty compared with kyphoplasty
    - Pain relief: In 8 of 10 non-randomized studies, vertebroplasty and kyphoplasty led to comparable pain reduction up to 2 years.
    - Function and quality of life: In 4 of 5 non-randomized studies, vertebroplasty and kyphoplasty patients demonstrated comparable improvements in ODI up to 2 years.

- Sacroplasty: Unable to draw conclusions due to very limited data.

Regarding safety, the authors stated that, while it appears that the rate of serious complications with associated symptoms are low for vertebroplasty and kyphoplasty, studies with long-term follow up for greater than five yeas are few, and comparative studies, especially randomized controlled trials, may have too few patients to detect more rare but serious outcomes.

Professional Societies/Organizations: The American Academy of Orthopaedic Surgeons (AAOS) published a clinical practice guideline and evidence report on the treatment of symptomatic osteoporotic spinal compression fractures in 2010. The guideline was based on a systematic review of studies published in English in peer reviewed journals in or after 1966. Additional study requirements included the following: enrollment of ten or more patients per group; results presented quantitatively; enrolled patients 18 years of age or older; not an in vitro, biomechanical or cadaver study; results for patients with osteogenesis imperfecta or solid metastatic tumors of the spine excluded or reported separately; and at least 50% patient follow-up (in studies with > 50% but < 80% follow-up, the study quality was downgraded). Results reported as post-hoc subgroup analyses were excluded. The guideline includes the following recommendations regarding vertebroplasty and kyphoplasty:

- We recommend against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. (Strength of recommendation: strong)

- Kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. (Strength of recommendation: weak)

Additional AAOS recommendations regarding treatment of osteoporotic compression fractures include:

- We suggest patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms suggesting an acute injury (0-5 days after identifiable event or onset of symptoms) and who are neurologically intact be treated with calcitonin for 4 weeks. (Strength of recommendation: moderate)
- Ibandronate and strontium ranelate are options to prevent additional symptomatic fractures in patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms. (Strength of recommendation: weak)
- It is an option to treat patients who present with an osteoporotic spinal compression fracture at L3 or L4 on imaging with correlating clinical signs and symptoms suggesting an acute injury and who are neurologically intact with an L2 nerve root block. (Strength of recommendation: weak)

The authors were unable to recommend for or against the following treatments (Strength of each recommendation: inconclusive):

- Bed rest, complementary and alternative medicine, or opioids/analgesics for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.
- Treatment with a brace for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.)
- A supervised or unsupervised exercise program for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.
- Electrical stimulation for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

A practice guideline for the performance of vertebroplasty developed in collaboratively by the American College of Radiology, American Society of Neuroradiology, Society of Neurointerventional Surgery, American Society of Spine Radiology, and the Society of Interventional Radiology, was revised in 2009. The guideline states that the major indication for vertebroplasty is the treatment of symptomatic osteoporotic or neoplastic vertebral body compression fracture(s) refractory to medical therapy. Failure of medical therapy is defined as minimal or no pain relief with the administration of prescribed analgesics, or adequate pain relief with narcotic dosages that produce undesirable side effects. The guideline includes the following indications for vertebroplasty:

- Painful osteoporotic or neoplastic vertebral compression fracture(s) refractory to medical therapy
- Symptomatic vertebral body microfracture (as documented by magnetic resonance imaging [MRI] or nuclear imaging, and/or lytic lesion seen on CT) without obvious loss of vertebral body height

A 2007 position statement on percutaneous vertebral augmentation developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and the American Society of Spine Radiology, states that percutaneous vertebral augmentation with vertebroplasty and kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures when performed in a manner in accordance with published standards. These procedures are offered only when traditional medical therapy has not provided pain relief or pain is substantially altering the patient's lifestyle.

Sacroplasty is not addressed in published specialty society statements or guidelines.

Use Outside the U.S.
National Institute for Health and Care Excellence (NICE) (United Kingdom): NICE technology appraisal guidance issued in April 2013 states that percutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, are recommended as options for treating osteoporotic vertebral compression fractures only in people who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging.

An additional recommendation made as part of the clinical guideline on metastatic spinal cord compression published in November 2008 states that vertebroplasty or kyphoplasty should be considered in patients who have vertebral metastases and no evidence of metastatic spinal cord compression or spinal instability, if they have either mechanical pain resistant to analgesia, or vertebral body collapse. Vertebroplasty or kyphoplasty for spinal metastases should only be performed after agreement between appropriate specialists, including an oncologist, interventional radiologist, and spinal surgeon, and in facilities where there is good access to spinal surgery.

Summary
Percutaneous vertebroplasty and kyphoplasty gained acceptance by some practitioners for the treatment of painful osteolytic lesions and osteoporotic compression fractures based on evidence from prospective and retrospective case series. The safety and efficacy of vertebroplasty had not been evaluated in randomized controlled trials, however. Two randomized controlled trials published in 2009, however, demonstrated a lack of improved outcomes with vertebroplasty compared to a sham procedure in patients with osteoporotic vertebral fractures. These studies constitute the highest quality evidence published to date. Guidelines from the American Academy of Orthopaedic Surgeons published in 2010, based on a systematic review of studies published in

peer reviewed journals, strongly recommend against vertebroplasty for the treatment of osteoporotic spinal compression fractures. Based on published evidence and specialty society opinion, as well as published technology assessments, vertebroplasty has not been demonstrated to result in improved outcomes compared to conservative medical treatment in patients with osteoporotic vertebral compression fractures. Vertebroplasty may be a reasonable treatment option, however, for selected patients with severe back pain secondary to destruction of the vertebral body due to osteolytic vertebral metastasis or multiple myeloma, or for painful and/or aggressive hemangioma or eosinophilic granuloma of the spine, when conservative medical management has failed to alleviate symptoms.

Kyphoplasty, also referred to as percutaneous vertebral augmentation, is a modification of vertebroplasty which includes expansion of the vertebra with an inflatable balloon tamp prior to the injection of bone cement. Although the published medical literature evaluating kyphoplasty is not robust, kyphoplasty has been shown in several non-randomized studies to reduce pain more than conservative medical treatment for periods of up to three years, and improved specific functional outcomes more than conservative medical treatment. Additional well designed clinical trials with long term follow-up are needed to define patient selection criteria and to determine the long-term safety and efficacy of this procedure. Kyphoplasty should therefore be reserved for carefully selected patients in whom conservative medical management has failed to alleviate symptoms.

Sacroplasty, a variation of vertebroplasty, is an evolving technique that has been proposed for the treatment of sacral insufficiency fractures. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of this procedure.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Percutaneous Kyphoplasty

Covered when medically necessary:

CPT®* Codes	**Description**
22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic
22524	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); lumbar
22525	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

Percutaneous Vertebroplasty

Covered when medically necessary:

CPT®* Codes	**Description**
22520	Percutaneous vertebroplasty, (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection, thoracic
22521	Percutaneous vertebroplasty, (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection, lumbar

22522	Percutaneous vertebroplasty, (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

HCPCS Codes	Description
S2360	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical
S2361	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical; each additional cervical vertebral body (List separately in addition to code for primary procedure)

Percutaneous Sacroplasty

Experimental/Investigational/Unproven/Not Covered for any indication:

CPT* Codes	Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device (when used) 1 or more needles
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device (when used), 2 or more needles

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